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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,600	03/24/2006	James Wilson	UPN-P3230USA	6834
270 7590 08/06/2008 HOWSON AND HOWSON SUITE 210 501 OFFICE CENTER DRIVE FT WASHINGTON, PA 19034			EXAMINER EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1633	
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			08/06/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/573,600

**Applicant(s)**

WILSON ET AL.

**Examiner**

Janet L. Epps-Ford

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 26, 27, 30, 32, 41, 43, 45 and 59-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 26, 27 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30, 32, 43, 45 and 59-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-4, 26-27, 30, 32, 41, 43, 45, and 59-61 are presently pending.

#### *Election/Restrictions*

2. Applicant's election without traverse of Group 7 (claims 30-32, 43 and 45) in the reply filed on 4/30/2008 is acknowledged.
3. Claims 1-4, 26-27, and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/30/2008.

#### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 30, 32, 43, 45, and 59-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al. (US 7198951; citations given from issued US Patent) or under 35 USC 102(a) as being anticipated by Gao et al. (WO03/052052)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Instant claim 30 recites the following: "[A]n adeno-associated virus (AAV) of serotype 9 comprising an AAV capsid and a heterologous molecule for delivery to a cell, wherein the AAV capsid is serologically related to a capsid of the sequence of amino acids 1 to 736 of SEQ ID NO: 123 and serologically distinct from a capsid protein of any of AAV1, AAV2, AAV3, AAV4, AAV5, AAV6, AAV7 or AAV8."

Gao et al. describes sequences of adeno-associated virus of serotype 9, Gao et al. also describes methods of using AAV9 in a method of AAV9 mediated delivery of therapeutic and immunogenic genes into cells. Although, the AAV9 of Gao et al. does not disclose a capsid comprising a sequence that is 100% identical amino acids 1 to 736 of SEQ ID NO: 123, absent evidence to the contrary, the disclosed teachings of sequences which encode AAV9, and the recombinant production of rAAV, anticipates the claimed invention to the extent that the AAV9 disclosed by Gao et al. is *serologically*

related to an AAV9 capsid of the sequence of amino acids 1 to 736 of SEQ ID NO: 123 as recited in the instant claims.

Gao et al. discloses an AAV9 comprising a vp1 capsid protein having an amino acid sequence of SEQ ID NO: 2 that has 88.1% identity to SEQ ID NO: 123 of the instant specification. According to the instant specification, the AAV9 of the instant invention have a capsid with an amino acid identity of at least 85% identity to SEQ ID NO: 123 of the instant application, see page 15, § F. Gao et al. also discloses this AAV9 comprising a minigene having AAV inverted terminal repeats and a heterologous gene, a composition comprising said AAV9 and a physiologically compatible carrier, and a method of delivering a transgene to a cell comprising contacting this AAV9 with a cell, see col. 51-52.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 30 and 32, 43, 45, and 59-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7198951. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant claims is anticipated by the claims in the issued US Patent.

As stated above the scope of instant claim 30, and those claims dependent therefrom, read on an adeno-associated virus (AAV) of serotype 9 comprising an AAV capsid and a heterologous molecule for delivery to a cell, wherein the AAV capsid is *serologically related* to a capsid of the sequence of amino acids 1 to 736 of SEQ ID NO: 123 and serologically distinct from a capsid protein of any of AAV1, AAV2, AAV3, AAV4, AAV5, AAV6, AAV7 or AAV8.

Since the AAV of the issued patent comprises an vp1 capsid protein having an amino acid sequence of SEQ ID NO: 2 that has 88.1% identity to SEQ ID NO: 123 of the instant specification and is disclosed as having a serotype of 9, absent evidence to the contrary the AAV virus recited in the claims of the issued US Patent is serologically related to the AAV capsid of amino acids 1 to 736 of SEQ ID NO: 123 of the instant application. According to the instant specification, the AAV9 of the instant invention have a capsid with an amino acid identity of at least 85% identity to SEQ ID NO: 123 of the instant application, see page 15, § F.

Therefore the scope of the instant claims is anticipated by the claims of the issued US patent.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 32, 43, 45, 59-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the following: "The AAV according to claim 30, wherein said AAV further comprises a minigene having AAV inverted terminal repeats and the heterologous gene operably linked to regulatory sequences which direct its expression in a host cell." The use of the term AAV as set forth in this claim and in claims 43, 45, 59-60 is vague and indefinite since there are multiple AAV's recited in independent claim 30, namely AAV1, AAV2, AAV3, AAV4, AAV5, AAV6, AAV7, AAV8, and AAV9.

Claim 61 recites the following:

"The adeno-associated virus according to claim 30, wherein the AAV9/HU.14 capsid protein is encoded by a nucleic acid sequence is selected from the group consisting of: vpl, nt 1 to 2211; vp2, nt 2532 to 2211; and vp 3, nt 2730 to 2211; wherein the nucleotides numbers are of AAV9/HU.14, SEQ ID NO: 3."

First, the term "nt" should be replaced with the full term "nucleotides" to avoid clarity issues. Secondly the range of nucleotides set forth as "2532 to 2211" and "2730 to 2211," cannot be interpreted, it is unclear what these ranges are intended to

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encompass since each of these nucleotide ranges refers to a larger nucleotide number than the last number in the range." Third, the phrase "wherein the AAV/HU.14 capsid" lacks antecedent basis in claim 30.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633

/J. L. E./  
Primary Examiner, Art Unit 1633